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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0053]

International Sanitary and Phytosanitary Standard-Setting Activities

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with legislation implementing the results of the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade, we are informing the public of the international standard-setting activities of the World Organization for Animal Health, the Secretariat of the International Plant Protection Convention, and the North American Plant Protection Organization, and we are soliciting public comment on the standards to be considered.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0053>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2018-0053, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0053> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue

SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For general information on the topics covered in this notice, contact Ms. Jessica Mahalingappa, Assistant Deputy Administrator for Trade and Capacity Building, International Services, APHIS, room 1132, USDA South Building, 14th Street and Independence Avenue SW., Washington, DC 20250; (202) 799-7121.

For specific information regarding standard-setting activities of the World Organization for Animal Health, contact Dr. Michael David, Director, International Animal Health Standards Team, National Import Export Services, VS, APHIS, 4700 River Road Unit 33, Riverdale, MD 20737; (301) 851-3302.

For specific information regarding the standard-setting activities of the International Plant Protection Convention, contact Dr. Marina Zlotina, IPPC Technical Director, International Phytosanitary Standards, PPQ, APHIS, 4700 River Road Unit 130, Riverdale, MD 20737; (301) 851-2200.

For specific information on the North American Plant Protection Organization, contact Ms. Patricia Abad, NAPPO Technical Director, International Phytosanitary Standards, PPQ, APHIS, 4700 River Road Unit 130, Riverdale, MD 20737; (301) 851-2264.

SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established as the common international institutional framework for governing trade relations among its members in matters related to the Uruguay Round Agreements. The WTO is the successor organization to the General Agreement

on Tariffs and Trade. U.S. membership in the WTO was approved by Congress when it enacted the Uruguay Round Agreements Act (Pub. L. 103-465), which was signed into law on December 8, 1994. The WTO Agreements, which established the WTO, entered into force with respect to the United States on January 1, 1995. The Uruguay Round Agreements Act amended Title IV of the Trade Agreements Act of 1979 (19 U.S.C. 2531 *et seq.*). Section 491 of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2578), requires the President to designate an agency to be responsible for informing the public of the sanitary and phytosanitary (SPS) standard-setting activities of each international standard-setting organization. The designated agency must inform the public by publishing an annual notice in the *Federal Register* that provides the following information: (1) The SPS standards under consideration or planned for consideration by the international standard-setting organization; and (2) for each SPS standard specified, a description of the consideration or planned consideration of that standard, a statement of whether the United States is participating or plans to participate in the consideration of that standard, the agenda for U.S. participation, if any, and the agency responsible for representing the United States with respect to that standard.

“International standard” is defined in 19 U.S.C. 2578b as any standard, guideline, or recommendation: (1) Adopted by the Codex Alimentarius Commission (Codex) regarding food safety; (2) developed under the auspices of the World Organization for Animal Health (OIE, formerly known as the Office International des Epizooties) regarding animal health and welfare and zoonoses; (3) developed under the auspices of the Secretariat of the International Plant Protection Convention (IPPC or the Convention) and the North American Plant Protection Organization (NAPPO) regarding plant health; or (4) established by or developed under any

other international organization agreed to by the member countries of the North American Free Trade Agreement (NAFTA) or the member countries of the WTO.

The President, pursuant to Proclamation No. 6780 of March 23, 1995 (60 FR 15845), designated the Secretary of Agriculture as the official responsible for informing the public of the SPS standard-setting activities of Codex, OIE, IPPC, and NAPPO. The United States Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) informs the public of Codex standard-setting activities, and USDA's Animal and Plant Health Inspection Service (APHIS) informs the public of OIE, IPPC, and NAPPO standard-setting activities.

FSIS publishes an annual notice in the *Federal Register* to inform the public of SPS standard-setting activities for Codex. Codex was created in 1962 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. It is the major international organization for encouraging international trade in food and protecting the health and economic interests of consumers.

APHIS is responsible for publishing an annual notice of OIE, IPPC, and NAPPO activities related to international standards for plant and animal health and representing the United States with respect to these standards. Following are descriptions of the OIE, IPPC, and NAPPO organizations and the standard-setting agenda for each of these organizations. We have described the agenda that each of these organizations will address at their annual general sessions, including standards that may be presented for adoption or consideration, as well as other initiatives that may be underway at the OIE, IPPC, and NAPPO.

The agendas for these meetings are subject to change, and the draft standards identified in this notice may not be sufficiently developed and ready for adoption as indicated. Also, while it is the intent of the United States to support adoption of international standards and to participate

actively and fully in their development, it should be recognized that the U.S. position on a specific draft standard will depend on the acceptability of the final draft. Given the dynamic and interactive nature of the standard-setting process, we encourage any persons who are interested in the most current details about a specific draft standard or the U.S. position on a particular standard-setting issue, or in providing comments on a specific standard that may be under development, to contact APHIS. Contact information is provided at the beginning of this notice under FOR FURTHER INFORMATION CONTACT.

OIE Standard-Setting Activities

The OIE was established in Paris, France, in 1924 with the signing of an international agreement by 28 countries. It is currently composed of 181 Members, each of which is represented by a delegate who, in most cases, is the chief veterinary officer of that country or territory. The WTO has recognized the OIE as the international forum for setting animal health standards, reporting global animal disease events, and presenting guidelines and recommendations on sanitary measures relating to animal health.

The OIE facilitates intergovernmental cooperation to prevent the spread of contagious diseases in animals by sharing scientific research among its Members. The major functions of the OIE are to collect and disseminate information on the distribution and occurrence of animal diseases and to ensure that science-based standards govern international trade in animals and animal products. The OIE aims to achieve these through the development and revision of international standards for diagnostic tests, vaccines, and the safe international trade of animals and animal products.

The OIE provides annual reports on the global distribution of animal diseases, recognizes the free status of Members for certain diseases, categorizes animal diseases with respect to their

international significance, publishes bulletins on global disease status, and provides animal disease control guidelines to Members. Various OIE commissions and working groups undertake the development and preparation of draft standards, which are then circulated to Members for consultation (review and comment). Draft standards are revised accordingly and are presented to the OIE World Assembly of Delegates (all the Members) for review and adoption during the General Session, which meets annually every May. Adoption, as a general rule, is based on consensus of the OIE membership.

The most recent OIE General Session occurred May 20 to May 25, 2018, in Paris, France. The Chief Trade Advisor for APHIS' Veterinary Services program serves as the official U.S. Delegate to the OIE at this General Session. The Deputy Administrator for APHIS' Veterinary Services program serves as the Alternate Delegate. Information about OIE draft Terrestrial and Aquatic Animal Health Code chapters may be found on the internet at <http://www.aphis.usda.gov/animal-health/export-animals-oie> or by contacting Dr. Michael David (see FOR FURTHER INFORMATION CONTACT above).

OIE Terrestrial and Aquatic Animal Health Code Chapters Adopted During the May 2018 General Session

Twenty nine Code chapters were amended, rewritten, or newly proposed and presented for adoption at the General Session. The following Code chapters are of particular interest to the United States:

1. *Chapters 1.7, 1.8, 1.9, 1.10, 1.11, and 1.12. Chapters on the application for official recognition by the OIE of either risk status or free status for various diseases.* The United States reminded the Code Commission to respect the process for circulating new and updated chapters

to allow member countries the time that is necessary to properly review and comment on such chapters.

2. *Chapter 4.3., Zoning and Compartmentalization.* This chapter was significantly revised and either introduced or clarified various concepts regarding zones.

3. *Chapter 4.X., Chapter on vaccination.* This is a new chapter that provides member countries with basic guidelines and recommendations when considering the use of vaccines for a control program.

4. *Chapter 6.7., Harmonization of national antimicrobial resistance surveillance and monitoring programmes.* References to conducting antimicrobial surveillance on “the animal’s immediate environment or the wide environment” was deleted.

5. *Articles 6.81 and 6.8.bis., Monitoring of the quantities and usage patterns of antimicrobial agents used in food producing animals.* This is an existing chapter, however definitions for *therapeutic use*, *non-therapeutic use*, and *growth promotion* were introduced. The terms *veterinary medical use* and *non-veterinary medical use* were replaced with the terms *therapeutic use* and *non-therapeutic use*, respectively.

6. *Chapter 6.13., Prevention and control of Salmonella in pigs.* Several articles were revised to improve clarity, particularly with regards to the definition of *commercial pigs*.

7. *Chapter 6.X., Introduction to recommendations for veterinary public health.* This was a newly adopted chapter.

8. *Article 7.1.1., Introduction to the recommendations for animal welfare.* This was an amendment to an existing chapter.

9. *Article 7.1.X., Guiding principles for the use of measures to assess animal welfare.* The phrase “and other relevant bodies” was reinserted. This was important since entities such as

universities and commodity groups often are the ones with the capability to collect data that can be used to set target values.

10. *Chapter 7.X., Animal welfare and pig production systems.* The United States supported the adoption of this new chapter, but requested that the Code Commission consider further comments that the United States will be submitting related to some inconsistencies between Articles 7.X.9 and 7.X.10 to address foraging and feeding behavior recommendations.

OIE Terrestrial Animal Health Code Chapters for Upcoming and Future Review

- *Chapter 1.4., Animal health surveillance.*
- *Chapter 4.Y., Official control of listed disease.* This will be a new chapter.
- *Chapter 4.Z., Introduction to recommendations for disease prevention and control.* This will be a new introductory chapter for section 4.
- *Chapter 7.Y., Killing of reptiles for their skins, meat and other products.* This will be a new chapter.
- *Articles 15.1.1.bis., 15.1.2., 15.1.3., and 15.1.22., Infection with African swine fever virus.*
- *Articles 1.6.1. to 1.6.4., Procedures for self-declaration and for official recognition by the OIE.*
- *Chapter 8.14., Infection with rabies virus.*

IPPC Standard-Setting Activities

The IPPC is a multilateral convention adopted in 1952 to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control. The WTO recognizes the IPPC as the standard setting body for plant health. Under the IPPC, the understanding of plant protection encompasses the protection of both cultivated and

non-cultivated plants from direct or indirect injury by plant pests. The IPPC addresses the following activities: Developing, adopting, and implementing international standards for phytosanitary (plant health) measures (ISPMs); harmonizing phytosanitary activities through adopted standards; facilitating the exchange of official and scientific information among countries; and providing technical assistance to developing countries that are contracting parties to the Convention.

The IPPC is deposited within the Food and Agriculture Organization of the United Nations, and is an international agreement of 183 contracting parties. National plant protection organizations (NPPOs), in cooperation with regional plant protection organizations, the Commission on Phytosanitary Measures (CPM), and the Secretariat of the IPPC, implement the Convention. The IPPC continues to be administered at the national level by plant quarantine officials, whose primary objective is to safeguard plant resources from injurious pests. In the United States, the NPPO is APHIS' Plant Protection and Quarantine (PPQ) program.

The 12th Session of the CPM took place from April 16 to 20, 2018, in Rome, Italy, at the Headquarters of the Food and Agriculture Organization of the United Nations. The Deputy Administrator for APHIS' PPQ program was the U.S. delegate to the CPM.

The CPM adopted the following standards at its 2018 meeting. The United States, represented by the Deputy Administrator for APHIS' PPQ program, participated in deliberations of these standards. The United States developed its position on each of these issues prior to the CPM session, which were based on APHIS' analyses and other relevant information from other U.S. Government agencies and interested stakeholders:

- Revision of ISPM 6: Surveillance.
- 2015 and 2016 amendments to ISPM 5: Glossary of phytosanitary terms.

- Revision of Annex 1 and Annex 2 to ISPM 15, for inclusion of the phytosanitary treatment sulphuryl fluoride fumigation and revision of the dielectric heating section.
- ISPM 42: Requirements for the use of temperature treatments as a phytosanitary measures.
- Phytosanitary treatment as Annex to ISPM 28: Phytosanitary treatments for regulated pests: PT 32 Vapour heat treatment for *Bactrocera dorsalis* on *Carica papaya*.
- Diagnostic protocols (DPs) as Annexes to ISPM 27: Diagnostic protocols for regulated pests.
 - DP 23: *Phytophthora ramorum*.
 - DP 24: *Tomato spotted wilt virus*, *Impatiens necrotic spot virus*, and *Watermelon silver mottle virus*.

In addition to adopting these plant health standards, the 2018 Commission meeting also progressed a number of plant health initiatives strategically important to the United States. These initiatives include advancing the development of a new IPPC strategic framework for 2020-2030 to set the top priorities for plant health and trade, launching a pilot of a global electronic certification system to support trade (ePhyto), developing programs aimed at improving the use and implementation of standards around the world, and creating a task force for addressing pests issues associated with the international movement of sea containers.

New IPPC Standard-Setting Initiatives, Including Those in Development

A number of expert working group (EWG) meetings or other technical consultations took place October 2017 through July 2018 on the topics listed below. These standard-setting initiatives are under development and may be considered for future adoption. APHIS intends to participate actively and fully in each of these working groups. APHIS developed its position on

each of the topics prior to the working group meetings. The APHIS position was based on technical analyses, information from other U.S. Government agencies, and relevant scientific information from interested stakeholders:

- Expert Working Group on Guidance on Pest Risk Management.
- Technical Panel for the Glossary of Phytosanitary Terms.
- Technical Panel on Diagnostic Protocols.
- Technical Panel on Phytosanitary Treatments.

For more detailed information on the above, contact Dr. Marina Zlotina (see FOR FURTHER INFORMATION CONTACT above).

PPQ actively works to achieve broad participation by States, industry, and other stakeholders in the development and use of international and regional plant health standards. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during the consultation periods. In 2018, six draft standards and one draft specification were open for consultation. APHIS posts links to draft standards on its website as they become available and provides information on the due dates for comments.¹ Additional information on IPPC standards (including the IPPC work program (list of topics²), standard-setting process, and adopted standards) is available on the IPPC website.³ For the most current information on official U.S. participation in IPPC activities, including U.S. positions on standards being considered, contact Dr. Marina Zlotina (see FOR FURTHER INFORMATION CONTACT above). Those wishing to provide comments on any of the areas of work being

¹ For more information on the IPPC draft ISPM consultation:

https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa_international/sa_phytostandards/ct_draft_standards.

² IPPC list of topics: <https://www.ippc.int/en/core-activities/standards-setting/list-topics-ippc-standards/>.

³ IPPC website: <https://www.ippc.int/>.

undertaken by the IPPC may do so at any time by responding to this notice (see ADDRESSES above) or by providing comments through Dr. Zlotina.

NAPPO Standard-Setting Activities

NAPPO, a regional plant protection organization created in 1976 under the IPPC, coordinates the efforts among the United States, Canada, and Mexico to protect their plant resources from the entry, establishment, and spread of harmful plant pests, while facilitating intra- and inter-regional trade. As the NPPO of the United States, APHIS' PPQ is the organization officially identified to participate in NAPPO. Through NAPPO, APHIS works closely with its regional counterparts and industries to develop harmonized regional standards and approaches for managing pest threats. NAPPO conducts its work through priority-driven annual projects approved by the NAPPO Executive Committee and conducted by expert groups, including subject matter experts from each member country and regional industry representatives. Project results and updates are provided during the NAPPO annual meeting. Projects can include the development of positions, policies, or technical documents, or the development or revision of regional standards for phytosanitary measures (RSPMs). Projects can also include implementation of standards or other capacity development activities such as workshops.

The 41st NAPPO annual meeting was held October 16 to 19, 2017, in Merida, Yucatan, Mexico. The meeting featured several strategic topics, including a 1-day symposium on surveillance in the NAPPO countries and the Americas. The NAPPO Executive Committee meetings took place on October 16 and 20, 2017, and February 15, 2018. The Deputy Administrator for PPQ is the U.S. member of the NAPPO Executive Committee.

The NAPPO expert groups, including member countries' subject matter experts, finalized the following regional standards, documents, products, and projects in 2017-2018:

- Completed an English language online training module on RSPM 12–Preparation of a Petition for First Release of a Non-indigenous Entomophagous Biological Control Agent.
- Organized and delivered the first International Symposium on Risk-Based Sampling in June 2017 in Baltimore, MD, which included 122 government, industry, and academic participants from 27 countries.
- Completed a NAPPO discussion document on Criteria for Evaluating Phytosanitary Seed Treatments. The NAPPO Executive Committee approved this document during the 2017 October NAPPO annual meeting.
- Completed a discussion document on Likelihood of Establishment. The NAPPO Executive Committee approved this document during the 2017 October NAPPO annual meeting.
- Issued via NAPPO's Phytosanitary Alert System (PAS): 29 Official Pest Reports and 6 Emerging Pest Alerts for FY 2018 (from October 2017 to July 2018).
- Conducted a review of RSPM 36 (Phytosanitary Guidelines for the Movement of Seed) and completed the archiving of RSPM 36 in-light of the newly adopted ISPM 38: International Movement of Seeds.

New NAPPO Standard-Setting Initiatives, Including Those in Development

The 2018 work program⁴ includes the following topics being worked on by NAPPO expert groups and NAPPO's Advisory and Management Committee. APHIS intends to participate actively and fully in the 2018 NAPPO work program. The APHIS position on each topic will be guided and informed by the best technical and scientific information available, as well as on relevant input from stakeholders. For each of the following, the United States will consider its position on any draft standard after it reviews a prepared draft. Information regarding the following NAPPO projects, assignments, activities, and updates on meeting times and locations may be obtained from the NAPPO website or by contacting Ms. Patricia Abad (see FOR FURTHER INFORMATION CONTACT above).

1. RSPM 9: Revision of Regional Standard for Phytosanitary Measures 9: Authorization of Laboratories for Phytosanitary Testing.
2. RSPM 35: Revision of Regional Standard for Phytosanitary Measures 35: Guidelines for the Movement of Stone and Pome Fruit Trees and Grapevines into a NAPPO Member Country.
3. ISPM 38 Implementation: Design and deliver a hemispheric (Americas focused) workshop to promote the understanding and implementation of ISPM 38: International Movement of Seeds.
4. Forestry Systems Approaches: Finalize a NAPPO Regional Standard for Phytosanitary Measures (RSPM 41) on the use of systems approaches to manage pest risks associated with the movement of wood.

⁴ NAPPO work program: <http://nappo.org/english/710/status-current-nappo-projects/>.

5. Lymantriids: Develop a NAPPO Science and Technology document on the risks associated with Lymantriids of concern to the NAPPO region, identifying potential species and pathways of concern.
6. Khapra Beetle: Develop a discussion document on a harmonized North American approach to preventing the introduction, establishment, and spread of khapra beetle in various pathways.
7. Biological Control: Develop online training module in Spanish on preparing a petition for first release of an entomophagous biological control agent.
8. Risk-Based Sampling: Complete and publish proceedings from 2017 International Risk-Based Sampling Symposium (organized by NAPPO) as well as Risk-Based Sampling Manual.
9. Asian Gypsy Moth: Validate specific risk periods for regulated Asian gypsy moth in countries of origin.
10. Foundation and Procedure documents: Continue to update and finalize various foundation or procedure documents.
11. Electronic Phytosanitary Certification: Provide assistance and technical support to the IPPC ePhyto Steering Group.
12. Phytosanitary Alert System: Continue to manage the NAPPO pest reporting system.
13. Update to Pest List for RSPM 3: Movement of Potatoes into a NAPPO Member Country.
14. Regional Collaboration: Collaboration (mainly information exchange) with the Interamerican Coordinating Group in Plant Protection (GICSV), via Technical Working Groups on ePhyto and citrus greening (HLB).

15. Stakeholder Engagement: Plan, coordinate and execute activities for the October 2018 NAPPO Annual Meeting in Tucson, Arizona, and publish the quarterly newsletter.

The PPQ Assistant Deputy Administrator, as the official U.S. delegate to NAPPO, intends to participate in the adoption of these regional plant health standards and projects, including the work described above, once they are completed and ready for such consideration.

The information in this notice contains all the information available to us on NAPPO standards under development or consideration. For updates on meeting times and for information on the expert groups that may become available following publication of this notice, visit the NAPPO website or contact Ms. Patricia Abad (see FOR FURTHER INFORMATION CONTACT above). PPQ actively works to achieve broad participation by States, industry, and other stakeholders in the development and use of international and regional plant health standards. Plant health stakeholders are strongly encouraged to comment on draft standards, documents, and specifications during consultation periods. APHIS posts links to draft standards on the Internet as they become available and provides information on the due dates for comments.⁵ Additional information on NAPPO standards (including the NAPPO Work Program, standard setting process, and adopted standards) is available on the NAPPO website.⁶ Information on official U.S. participation in NAPPO activities, including U.S. positions on standards being considered, may also be obtained from Ms. Abad. Those wishing to provide

⁵ For more information on the NAPPO draft RSPM consultation:
https://www.aphis.usda.gov/aphis/ourfocus/planthealth/sa_international/sa_phytostandards/ct_draft_standards.

⁶ NAPPO website: <http://nappo.org/>.

comments on any of the topics being addressed in the NAPPO work program may do so at any time by responding to this notice (see ADDRESSES above) or by transmitting comments through Ms. Abad.

Done in Washington, DC, on September 27, 2018.

Kevin Shea,

Administrator,

Animal and Plant Health Inspection Service.

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